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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,342

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Bernd Lang

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EXAMINER

HICKS, VICTORIA J

ART UNIT

PAPER NUMBER

3772

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,342	Applicant(s) LANG ET AL.	
	Examiner VICTORIA HICKS	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 25-38 is/are pending in the application.
- 4a) Of the above claim(s) 13-24 and 39-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 25-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/9/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>EP1099452 description, claims, drawings, bibdata (4 documents)</u> . |

DETAILED ACTION

This action is in response to the amendment filed on June 8, 2009.

Election/Restrictions

Applicant's election without traverse of claims 1-12 and 25-38 in the reply filed on 6/8/09 is acknowledged.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The abstract of the disclosure is objected to because the abstract contains legal phraseology ("comprising") which should be removed. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 recites the limitation "the dish-shaped body" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. The Examiner is unable to discern what the Applicant is attempting to claim using the term “a fixing profiling.”

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner is unable to discern what the Applicant is attempting to claim using the term “a folding bellows portion.”

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3-12, 26-28, 29, 31-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lang et al. (EP 1099452).

In regards to claim 1, Lang et al. teaches in Figures 1a and 1e a mask pad (1) with a receiving opening (n) which in the position of application of the breathing mask coincides at least with the nose and/or mouth opening region of a user of the mask, and a sealing lip (4, 9, 23) that extends around the receiving opening (n) and which in the application position fits on the surface of the face of the user of the mask. In [0041] Lang et al. teaches that the sealing lip (4, 9, 23) is formed from an elastomer (elastomeric) material. In [0041] and Figure 7 Lang et al. teaches at least one zone of thickened cross-section (23, 33) is provided in the mask pad (24) and that the mask pad (24) material of the zone of thickened cross-section (23, 33) has different material

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properties in such a way that the Shore hardness (which increases with the amount of crosslinking) of the mask pad (24) in the edge region (33) of the zone of thickened cross-section (23, 33) is higher than in the region which is at the core or at least near the core (23), of the zone of thickened cross-section.

In regards to claim 3, Lang et al. substantially teaches the apparatus of claim 1 (see rejection of claim 1 above). Lang et al. teaches in [0037] that in the core region (23) of the zone of thickened cross-section (23, 33) the material has gel-like properties (formed from gel-like cured materials).

In regards to claim 4, Lang et al. substantially teaches the apparatus of claim 1 (see rejection of claim 1 above). Lang et al. teaches in [0041] that the different material properties in the region of the zones of thickened cross-section (23, 33) are caused by different degrees of crosslinking of the material.

In regards to claim 5, Lang et al. substantially teaches the apparatus of claim 1 (see rejection of claim 1 above). Lang et al. teaches in Figure 7 that the zones of thickened cross-section (23, 33) adjoin the sealing lip (9).

In regards to claim 6, Lang et al. substantially teaches the apparatus of claim 1 (see rejection of claim 1 above). Lang et al. teaches in Figure 7 that the zone of thickened cross-section (23, 33) in the application position is seated at least portion-wise on the surface of the face of the user of the mask. Lang et al. teaches in [0040] that the sealing lip (24) is designed for use approximate to the face of the user.

In regards to claim 7, Lang et al. substantially teaches the apparatus of claim 1 (see rejection of claim 1 above). Lang et al. teaches in Figure 7 that the zone of

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thickened cross-section (23, 33) in the application position is seated at least portion-wise on the inward side (approximate the inner face 34 toward the dish-shaped body 1) of the face sealing lip (24), which is remote from the from the surface of the face of the user of the mask.

In regards to claim 8, Lang et al. substantially teaches the apparatus of claim 1 (see rejection of claim 1 above). Lang et al. teaches in [0041] and Figure 7 that the zones of thickened cross-section (23, 33) are formed of at least two elastomer compound materials (23, 33) which are prepared differently (they are crosslinked in different degrees).

In regards to claim 9, Lang et al. substantially teaches the apparatus of claim 1 (see rejection of claim 1 above). Lang et al. teaches in Figure 1a that it (4) is adapted to be fitted to a dish-shaped body (1) formed by a hard shell member.

In regards to claim 10, Lang et al. substantially teaches the apparatus of claim 1 (see rejection of claim 1 above). Lang et al. teaches in [0026] that the sealing pad device (4) is formed integrally with the dish-shaped body (1).

In regards to claim 11, Lang et al. substantially teaches the apparatus of claim 1 (see rejection of claim 1 above). Lang et al. teaches in Figure 7 that the zones of thickened cross-section (23, 33) are suspended in the application direction at least in a portion-wise manner. In [0041] Lang et al. teaches that the zones of thickened cross-section (23, 33) are made of resiliently yielding (elastomeric) material. Lang et al. teaches in [0040] that the sealing lip (24), which includes the zones of thickened cross-

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section (23, 33), is designed for use approximate to the face of the user (the application direction).

In regards to claim 12, Lang et al. substantially teaches the apparatus of claim 1 (see rejection of claim 1 above). Lang et al. teaches in Figures 1 and 3b that the sealing lip (9) is resiliently coupled by way of a folding structure to the zone of thickened cross-section.

In regards to claim 26, Lang et al. teaches in Figures 1a and 1e a mask pad (1) with a receiving opening (n) which in the position of application of the breathing mask coincides at least with the nose and/or mouth opening region of a user of the mask, and a sealing lip (4, 9, 23) that extends around the receiving opening (n) and which in the application position fits on the surface of the face of the user of the mask. In [0041] Lang et al. teaches that the sealing lip (4, 9, 23) is formed from an elastomer (elastomeric) material. In [0041] and Figure 7 Lang et al. teaches at least one zone of thickened cross-section (23, 33) is provided in the inner region of the mask pad (24) and that the mask pad (24) material of the zone of thickened cross-section (23, 33) has gel-like material properties, wherein the zone of thickened cross-section (23, 33) is formed by insertion of a gel-like cross-linked elastomer body into a fixing structure in the internal space of the mask pad device. Further the claim discloses the limitation "formed by insertion of a gel-like crosslinked elastomer body into a fixing structure provided in the internal space of the mask pad device" in the last two lines of the claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a

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product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

In regards to claim 27, Lang et al. substantially teaches the apparatus of claim 26 (see rejection of claim 26 above). Lang et al. teaches in [0037] and Figure 3b that the gel-like crosslinked body (9) is of a horse-like configuration and in the application position is capable of extending over the bridge of the nose of the user of the mask.

In regards to claim 28, Lang et al. substantially teaches the apparatus of claim 26 (see rejection of claim 26 above). Lang et al. teaches in [0037] and Figures 1, 1a and 1e that the gel-like crosslinked body (9) is of a ring-like configuration, following the sealing lip (4, 9, 23), extending around a mouth and/or nose opening.

In regards to claim 29, Lang et al. teaches in Figures 1a and 1e a mask pad (1) with a receiving opening (n) which in the position of application of the breathing mask coincides at least with the nose and/or mouth opening region of a user of the mask, and a sealing lip (4, 9, 23) that extends around the receiving opening (n) and which in the application position fits on the surface of the face of the user of the mask. In [0041] Lang et al. teaches that the sealing lip (4, 9, 23) is formed from an elastomer (elastomeric) material. In Figure 7 Lang et al. teaches at least one receiving pocket portion (34) and provided in the receiving pocket portion (34) is a cushion body (23), wherein the configuration of the pocket portion (34) is established such that the sealing lip (4, 9, 23) device defined a skin contact zone in which the sealing lip (4, 9, 23) device

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can be urged against the surface of the face by the cushion body (23). In [0041] Lang et al. teaches that the cushion body is formed of a gel material.

In regards to claim 31, Lang et al. teaches in [0025] that the forehead pad base body (1) is made from an elastomer material. In Figures 4 and 7 Lang et al. teaches that the base body (1) has a coupling portion (34) for fixing the forehead pad (24) to a forehead support device (1) and a stem portion for radially yieldingly mounting a forehead contact portion provided (24) for bearing against a forehead surface, wherein the forehead pad (24) has a zone of thickened cross-section and in the zone is provided with a gel or foam material (23).

In regards to claim 32, Lang et al. teaches in [0041] and Figure 7 a base body (24) material made from an elastomer profile material (23, 33), wherein the base body (24) has a profile cross-section with at least one zone of thickened cross-section (23, 33) and the elastomer material is processed in such a way that the Shore hardness (which increases with the amount of crosslinking) of the profile material is higher in the edge region (33) of the zone of thickened cross-section than in the core or in the region near the core (23) of the zone of thickened cross-section.

In regards to claim 33, Lang et al. substantially teaches the apparatus of claim 32 (see rejection of claim 32 above). Lang et al. teaches in [0041] and Figure 7 that in the core region (23) of the zone of thickened cross-section (23, 33) that material has gel-like material properties.

In regards to claim 34, Lang et al. substantially teaches the apparatus of claim 32 (see rejection of claim 32 above). Lang et al. teaches in [0041] and Figure 7 that the

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differing material properties in the region of the zone of thickened cross-section (23, 33) are caused by differing degrees of material crosslinking.

In regards to claim 35, Lang et al. substantially teaches the apparatus of claim 32 (see rejection of claim 32 above). Lang et al. teaches in Figure 7 that the sealing structure (24) includes a sealing lip (9) and the zone of thickened cross-section (23, 33) adjoins the sealing lip (9).

In regards to claim 36, Lang et al. substantially teaches the apparatus of claim 32 (see rejection of claim 32 above). Lang et al. teaches in [0041] and Figure 7 that the zone of thickened cross-section (23, 33) is formed from at least two differently prepared (they are crosslinked in different degrees) elastomer compound systems (23, 33).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al. (EP 1099452) in view of Lithgow et al. (US publication 2009/0178679).

In regards to claim 2, Lang et al. substantially teaches the apparatus of claim 1 (see rejection of claim 1 above). Lang et al. does not teach that the shore hardness of the mask pad in the region of the zones which in application position are near the forehead or the bridge of the nose is lower than in the region of the peripheral zones

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near the cheeks, top lip or sides of the nose. However, Lithgow et al. teaches in [0023] an analogous device in which the mask pad (cushion) has a gusset portion. In [0133] Lithgow et al. teaches that this gusset portion (which is part of the mask pad) in the region of the zones which in application position are near the forehead or the bridge of the nose is lower (because the material is thinner) than in the region of the peripheral zones near the cheeks, top lip or sides of the nose (where the material is thicker). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the mask pad taught by Lang et al. with the varying Shore hardness taught by Lithgow et al. because this element is known to provide a smaller force component on the bridge of the nose, which improves the comfort of the user.

In regards to claim 30, Lang et al. substantially teaches the apparatus of claim 29 (see rejection of claim 29 above). Lang et al. does not teach that the cushion body is subdivided into segments. However, Lithgow et al. teaches in [0114] and Figure 2B an analogous device in which the cushion body (14) is subdivided into segments (24, 26, 28). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the cushion body taught by Lang et al. with the segments taught by Lithgow et al. because this element is known to enable the contact force applied to sensitive region's on the patient's face to be minimized, as Lithgow et al. teaches in [0114].

3. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over
Lang et al. (EP 1099452) in view of Le Mitouard (US patent 5,429,683).

In regards to claim 25, Lang et al. teaches in Figures 1a and 1e a mask pad (1) with a receiving opening (n) which in the position of application of the breathing mask coincides at least with the nose and/or mouth opening region of a user of the mask, and a sealing lip (4, 9, 23) that extends around the receiving opening (n) and which in the application position fits on the surface of the face of the user of the mask. In [0041] Lang et al. teaches that the sealing lip (4, 9, 23) is formed from an elastomer (elastomeric) material. In [0041] and Figure 7 Lang et al. teaches at least one zone of thickened cross-section (23, 33) is provided in the mask pad (24). Lang et al. does not teach that the mask pad material of the zone of thickened cross-section is foamed in such a way that in the region of the zone of thickened cross-section the mask pad forms a foam cushion. However, Le Mitouard teaches in Figure 3 and column 3, lines 29-32 an analogous device in which the mask pad (6) material of the zone of thickened cross-section (6a) is foamed in such a way that in the region of the zone of thickened cross-section (6a) the mask pad (6) forms a foam cushion. It would have been obvious to one having ordinary skill in the art at the time of invention to modify the zone of thickened cross-section taught by Lang et al. with the foam cushion taught by Le Mitouard because this element is known to provide a comfortable cushioning surface for the user.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA HICKS whose telephone number is (571)270-7033. The examiner can normally be reached on Monday through Thursday, 7:00am-5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. H./

Examiner, Art Unit 3772

8/13/09

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767